exchange members as "fins" would actually make a reader of the claims less certain of the scope of the claims. For this reason, Applicants ask the Office to withdraw the rejection of the claims as indefinite under 35 U.S.C. §112, second paragraph, for use of the term "heat exchange member."

Additionally, the Office rejects the claims as indefinite under 35 U.S.C. §112, second paragraph, for use of the term "biopharmaceutical product." As noted above, the actual rejection of claims 1-20 and 22-35 is moot due to cancellation of those claims. However, applicant addresses the substantive nature of the rejection as "biopharmaceutical product" appears in currently pending claims 36-68.

The term "biopharmaceutical product" is actually well understood in the art. A reasonable definition of biopharmaceutical product is: a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulatory agencies. Support for Applicants' position that this definition is well understood may be found in the accompanying copies of Declarations of Chris J. Burman, V. Bryan Lawlis, Jr., and David A. Vetterlein, originally submitted in a response filed in United States Patent Application Serial Number 08/895,782. As can be seen by inspection, the Declarants, each of whom has at least around two decades of experience in the industry, are unanimous in agreeing on the definition. (Decl. of Burman at ¶ 7, Decl. of Lawlis at ¶ 7, and Decl. of Vetterlein at ¶ 7.)

The list of examples of biopharmaceutical products given in the specification include those that fall within the definition given above and known in the art. For example, a potential infringer would know that not just any protein is within the scope of the claimed invention. Rather, the protein must be a biopharmaceutical product according to the above definition.

In light of the above, the term "biopharmaceutical product" is not indefinite. Applicants therefore request the withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, of the claim term "biopharmaceutical product" as being indefinite.

Rejections under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a):

Claims 1-20 and 22-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,220,954 to Longardner et. al. ("Longardner). Applicants traverse this rejection.

First, Applicants point out that claims 1-20 and 22-35 have been cancelled, making moot their rejection. However, Applicants address the substantive nature of the rejections as they might be applied to newly added claims 36-68.

Applicants note that claims 36-68 require a biopharmaceutical product. Longardner teaches no such biopharmaceutical product. Rather, it teaches a heat exchanger for a phase change material, such as hydrated salt phase change compositions (Column 1, lines 40-42).

The cited reference does not teach or suggest the claim element "biopharmaceutical product." To anticipate a claim, the cited reference must teach every element of the claim. MPEP § 2131. Accordingly, Applicants request withdrawal of the rejection of the claims under 35 U.S.C. § 102(b) as being clearly anticipated by Longardner. Further, the cited reference fails to teach or suggest all of the claim limitations. Accordingly, a proper prima facie case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the allowance of currently pending claims 36-68 despite the rejection of cancelled claims 1-20 and 22-35.

Claim 13 is rejected under 35 U.S.C. §. 103(a) as being unpatentable over Longardner as applied to claim 1 above, and further in view of United States Patent 2,391,876 to Brown ("Brown"). Applicants traverse this rejection.

First, Applicants point out that claim 13 has been cancelled, making moot its rejection. However, Applicants address the substantive nature of the rejection as it might be applied to newly added claims 36-68.

Applicants note that claims 36-68 require a biopharmaceutical product. Longardner teaches no such biopharmaceutical product. Rather, it teaches a heat exchanger for a phase change material, such as hydrated salt phase change compositions (Column 1, lines 40-42). Brown does not remedy Longardner's deficiencies, as it is directed to a material-treating tank and discloses nothing about biopharmaceutical products.

The cited reference does not teach or suggest the claim element "biopharmaceutical product." The combination of the cited references fails to teach or suggest all of the claim limitations. Accordingly, a proper prima facie case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the allowance of currently pending claims 36-68 despite the rejection of cancelled claim 13.

The Office rejects claims 1-20, and 22-35 under 35 U.S.C. §102(a) and 35 U.S.C. §102(b), as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over R. Wisniewski and V. Wu, Large-Scale Freezing and Thawing of Biopharmaceutical Products, PharmTech Conf. (September 1996) ("Wisniewski"). Applicants traverse this rejection.

First, Applicants point out that claims 1-20 and 22-35 have been cancelled, making moot their rejection. However, Applicants address the substantive nature of the rejections as they might be applied to newly added claims 36-68.

Next, Applicants point out that Wisniewski is not properly prior art under 35 U.S.C. §102. Therefore, it is not available as prior art in such a rejection. On this ground alone, the rejection should be withdrawn.

However, Applicants address Wisniewski substantively, as the Office has indicated concern about it and "underlying use known to others."

Wisniewski contains absolutely no discussion about the thermal transfer bridges required by the claimed invention. While Figure 1 of Wisniewski may bear a superficial resemblance to the claimed invention, the reality is that the structure of Wisniewski is not capable of forming thermal transfer bridges as one of skill in the art could readily determine by inspection of Wisniewski. No discussion of the importance of thermal transfer bridges in enhanced heat transport (Specification at page 12, lines 9-16) occurs anywhere in Wisniewski. Wisniewski does not provide any teaching or suggestion of the recited thermal transfer bridges.

The cited reference does not teach or suggest the claim element "thermal transfer bridge." To anticipate a claim, the cited reference must teach every element of the claim. MPEP § 2131. Accordingly, Applicants request withdrawal of the rejection of the claims under 35 U.S.C. § 102(b) as being clearly anticipated by Wisniewski. Further, the cited reference fails to teach or suggest all of the claim limitations. Accordingly, a proper prima facie case of obviousness has not been made out. MPEP § 2143.03. Applicants therefore request the allowance of currently pending claims 36-68 despite the rejection of cancelled claims 1-20 and 22-35.

Conclusion:

Applicants submit that currently pending claims 36-68 are in condition for allowance. Prompt consideration and timely issuance of all pending claims is respectfully requested. Any questions regarding this matter may be addressed to the undersigned at (650) 849-3438.

Respectfully submitted,

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